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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

JUL 16 1999

Re: Docket No. 98N-0583 "Proposed Rule for Exports: Notification and Recordkeeping Requirements"

Dear Sir/Madam:

The R.W. Johnson Pharmaceutical Research Institute (PRI) is a U.S.-based research and development corporation who distributes drugs and biologics for investigational use throughout the world. PRI supports comments previously made by PhRMA on the draft guidance documents, "FDA Draft Guidance for Industry; Draft Guidance on Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996", which was the subject of the Federal Register Notice of June 12, 1998.

We note that the current Proposed Rule published in the Federal Register of April 2, 1999, incorporates many of the same requirements that were the subject of comments to the June 12, 1998 Notice, without any reference to those comments. We, therefore, appreciate the opportunity to comment on this proposed rule and reiterate some comments, which were already made in response to the June 12, 1998 FR Notice.

Under 21 CFR 1.101 (b)(2) the proposed rule requires that, "records demonstrating that the product does not conflict with the laws of the importing country....." be obtained from an"....appropriate government agency, body or other authorized body stating that the product has marketing approval or does not conflict with the country's laws". As stated in previous comments, this requirement would impose additional, time consuming, burdens to the exportation of drugs which would conflict with the intent of the 1996 Export Act. The type of letter that is required is often difficult, if not impossible, to obtain and may even violate the laws of the importing country. Foreign governments do not normally have a mechanism for the issuance of letters in compliance with this section and some, where it does not violate their local laws, object to the necessity of providing this type of letter. It also seems to be in conflict with Congress' intent to better promote and equalize our role in international trade. A company review of the country's laws and documentation of that review should be sufficient to fulfill the requirement of "....does not conflict with the importing country's laws". Alternatively, documentation received from the local country's ethics committee approving the conduct of the clinical study should be sufficient to fulfill this requirement.

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98N-0583

We also disagree with the Proposed Rule in that it continues to prohibit transshipment of drugs from one Tier 1 country to another Tier 1 country or from a Tier 1 country to a Tier 2 country. We realize that the 1996 Export Act was silent on this matter but it must be recognized that once clinical trial materials are imported into a listed country (Tier 1 country), they become subject to the laws and regulations of the local competent authorities in that listed country. This means that any decision on whether the imported materials should be allowed to be shipped to another country must be made according to the local laws governing such exports in the original importing country. The practice of banning transshipments would restrict the ability of companies to continue to conduct multi-country, multi-center clinical studies outside of the United States. It should be the responsibility of the firm to ensure that all clinical investigations are conducted in accordance with the laws of any foreign country to which the drug is to be exported. In regard to Recordkeeping, the exporting company should only have to keep records of shipments to those countries to which it directly exports drugs. It would then become the responsibility of the importing company to keep records of the countries to which it transships the drug.

We strongly agree that the submission requirement of proposed 21 CFR 1.101 (d)(1)(iv) should allow periodic notifications and we recommend that these notifications be made to the Agency on an annual basis or, at least, no more often than on a bi-annual basis as such submissions will be very burdensome on the pharmaceutical industry and on the Agency resources as well. We further suggest that they be prepared in tabular form and submitted directly, electronically if at all possible, or on a computer disc if electronic transfer is not possible. We note that the proposal speaks of notification when the exporter first begins to export to a given country. We assume that this would be the only notification required. We would not expect to have to notify the Agency every time a subsequent shipment is made.

For products approved in the United States, used for an unapproved use in a foreign country, we do not believe we should be required to report such shipments to the Agency. To be completely compliant we would be required to report each shipment made outside of the United States. This is not consistent with the role of regulatory relief and appears to be beyond the jurisdiction of the Agency. Foreign Health Authorities are fully empowered to approve labelling and/or indications which they deem appropriate.

The R.W. Johnson Pharmaceutical Research Institute appreciates the opportunity to comment on FDA's Proposed Rule on the Notification and Recordkeeping Requirements for persons exporting human drugs, biologics, animal drugs, food and cosmetics which may not be marketed or sold in the United States. We trust you will find these comments helpful in finalizing these regulations.

Very truly yours,

The R.W. Johnson
Pharmaceutical Research Institute

for L. B. Dzewucki
Gary Shangold, M.D.
Vice President
Regulatory Franchise Leader

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